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Inspections, Compliance, Enforcement, and Criminal Investigations

Alexia Foods, Inc 11/16/11



Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, Maryland

**WARNING LETTER
NOV 16, 2011**

**OVERNIGHT MAIL
RETURN RECEIPT REQUESTED**

Alex Dzieduszycki, CEO/President
Alexia Foods, Inc.
51-02 21st Street, #3B
Long Island City, New York 11101

Dear Mr. Dzieduszycki:

The U.S. Food and Drug Administration (FDA) has reviewed the labels for your Alexia brand Roasted Red Potatoes & Baby Portabella Mushrooms products. Based on our review, we have concluded that these products are in violation of the Federal Food, Drug, and Cosmetic Act (the Act). You can find copies of the Act and the FDA regulations through links in FDA's home page at <http://www.fda.gov>¹.

Your Alexia brand Roasted Red Potatoes & Baby Portabella Mushrooms product is misbranded within the meaning of section 403(a)(1) of the Act [21 U.S.C. 343(a)(1)], which states that a food shall be deemed to be misbranded if its labeling is false or misleading in any particular. The phrase "All Natural" appears at the top of the principal display panel on the label. FDA considers use of the term "natural" on a food label to be truthful and non-misleading when "nothing artificial or synthetic...has been included in, or has been added to, a food that would not normally be expected to be in the food." [58 FR 2302, 2407, January 6, 1993].

Your Alexia brand Roasted Red Potatoes & Baby Portabella Mushrooms product contains disodium dihydrogen pyrophosphate, which is a synthetic chemical preservative. Because your products contain this synthetic ingredient, the use of the claim "All Natural" on this product label is false and misleading, and therefore your product is misbranded under section 403(a)(1) of the Act.

We note that your Alexia brand products market a number of food products with the "All Natural" statement on the label. We recommend that you review all of your product labels to be consistent with our policy to avoid additional misbranding of your food products.

This letter is not intended to be an all-inclusive review of your products and their labeling. It is your responsibility to ensure that all of your products and labeling comply with the Act and its implementing regulations. You should take prompt action to correct the violations cited in this letter. Failure to do so may result in enforcement action without further notice. Such action may include, but is not limited to,

seizure or injunction.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific actions you are taking to correct these violations and to prevent similar violations. You should include in your response documentation, such as revised labels or other useful information, that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining violations.

Your written response should be sent to Latasha Robinson, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions, please contact Ms. Robinson at 301-436-1890.

Sincerely yours,
/S/
Michael W. Roosevelt
Acting Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

cc: New York District Office

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1. <http://www.fda.gov/>